World J Surg (2011) 35:1651–1655
DOI 10.1007/s00268-011-1131-6

World Journal of Surgery

Does Prophylactic Biologic Mesh Placement Protect Against the Development of Incisional Hernia in High-risk Patients?

O. H. Llaguna · D. V. Avgerinos · P. Nagda · D. Elfant · I. M. Leitman · E. Goodman

Published online: 6 May 2011

Abstract
Background The purpose of this study was to determine whether the prophylactic use of a biologic prosthesis protects against the development of incisional hernia in a high-risk patient population.
Methods A prospective, nonrandomized trial was conducted on 134 patients undergoing open Roux-en-Y gastric bypass by a single surgeon, at two institutions, from January 2005 to November 2007. At Hospital A, all patients ($n = 59$) underwent fascial closure of the abdominal midline wound with the prophylactic placement of a biologic mesh (AlloDerm®) in an in-lay fashion. Patients at Hospital B ($n = 75$) underwent primary abdominal wall closure using #1 PDS in a running fashion. Data collected included patient demographics, abdominal wall closure technique, postoperative wound complications, follow-up period, and incidence of incisional hernia.
Results During the study period 134 patients (mean age = 40.4 years, 80.7% female) underwent open Roux-en-Y gastric bypass (59.7% mesh, 41.5% nonmesh). Twenty-eight patients were excluded from the analysis secondary to a short follow-up period (mesh = 13, nonmesh = 11) and/or reoperative surgery unrelated to the development of an incisional hernia (mesh = 2, nonmesh = 2). The mean follow-up period was 17.3 ± 8.5 months. The overall incidence of incisional hernia was 11.3% (95% CI: 5.2–17.45). The incidence of incisional hernia was significantly lower in the mesh group versus the nonmesh group (2.3 vs. 17.7%, $P = 0.014$). In a multivariate logistic regression model that adjusted for age, sex, body mass index, albumin, smoking, diabetes, prior surgery, seroma formation, weight loss, and mesh placement, the development of incisional hernia was found to be associated with smoking (adjusted odds ratio [OR] 8.46, 95% CI: 1.79–40.00, $P = 0.007$) while prophylactic mesh was noted to be protective against hernia development (adjusted OR 0.06, 95% CI: 0.006–0.69, $P = 0.02$).
Conclusion The prophylactic use of biologic mesh for abdominal wall closure appears to reduce the incidence of incisional hernia in patients with multiple risk factors for incisional hernia development.

Introduction

The traditionally recommended method of abdominal wall closure following laparotomy includes the use of a non-absorbable or slowly absorbing running suture with a 1 cm distance between stitches and the fascial margin. Despite technical improvement and adherence to principles, the overall incidence of incisional hernia following laparotomy remains reported to be between 11 and 23% [1–3]. Although patient-related risk factors such as a history of smoking, morbid obesity, pulmonary disease, abdominal aortic aneurysmal disease, prior abdominal surgery, or surgical site infections [4] cannot be controlled, modifications in the standard abdominal wall closure in pre-identified high-risk patient populations may reduce the

Presented at the 4th Annual Academic Surgical Congress, Fort Myers, FL, February 3-6 2009.

O. H. Llaguna (✉)
Division of Surgical Oncology and Endocrine Surgery, University of North Carolina, 170 Manning Drive, 1150 Physicians Office Building, Chapel Hill, NC 27599, USA
e-mail: omarllaguna.md@gmail.com

D. V. Avgerinos · P. Nagda · D. Elfant · I. M. Leitman · E. Goodman
Department of Surgery, Beth Israel Medical Center, Albert Einstein College of Medicine, New York, NY, USA

incidence of postoperative incisional hernias. One simple and feasible modification may be the prophylactic placement of subfascial prosthetic materials at the time of initial laparotomy.

While many studies validate the use of mesh for incisional hernia repair [5–11], few attempt to prove its usefulness in the prophylaxis of incisional hernia development. Although limited, the available data suggest that the prophylactic use of a nonabsorbable mesh at the time of initial laparotomy confers protection against hernia development [12–16]. Surgeons, however, are appropriately hesitant to adopt this practice, citing the paucity of data demonstrating the proposed technique's effectiveness and concerns about the placement of permanent mesh at the time of a potentially contaminated case. To help nullify these concerns, we suggest that AlloDerm® (LifeCell Corp., Branchburg, NJ), a biologic acellular matrix prosthetic mesh that has been found to be safe to use in contaminated cases [17, 18], may be ideal for prophylactic mesh placement, obviating the concern for infectious complications. The purpose of this study was to determine whether the prophylactic use of a biologic mesh is protective against the development of incisional hernia in a high-risk patient population, and if so, is it at the cost of added morbidity.

Methods

A prospective, nonrandomized trial was conducted on 134 patients undergoing open Roux-en-Y gastric bypass by a single surgeon, at two institutions, from January 2005 to November 2007. At Hospital A, all patients ($n = 59$, 44%) received prophylactic placement of a biologic mesh (AlloDerm) in an in-lay fashion during abdominal wall closure as an institutionally approved internal review board protocol. A 16 cm × 6 cm piece of mesh was routinely used. Given the biologic mesh's flexibility and smooth texture, which makes handling difficult, a moistened medium-sized malleable ribbon was placed underneath and used for positioning and stabilization. The mesh was placed below the fascia with several interrupted #1 polydioxanone sulfate (PDS®, Ethicon, Somerville, NJ) monofilament sutures, and the fascia was closed in a primary running fashion also with #1 PDS with a 1 cm distance between stitches and the fascial margin. Patients at Hospital B ($n = 75$, 56%) underwent primary abdominal wall closure using #1 PDS in a similar running fashion. At both institutions the primary surgeon performed the entire abdominal wall closure to minimize variability in technique. Routine follow-up consisted of laboratory work, weight loss assessment, and physical examination 1 week after discharge, monthly for 3 months, then every 6 months for 2 years. Incisional hernias were defined as a palpable fascial defect or visible protrusions at or near the surgical incision at rest or with valsalva. Imaging studies were performed only when clinically warranted. Data collected included patient demographics, abdominal wall closure technique (mesh versus nonmesh), postoperative wound complications, follow-up period, and incidence of incisional hernia. Data were analyzed using SPSS for Windows v16 (SPSS Inc., Chicago, IL). A P value less than 0.05 was considered statistically significant.

Results

During the study period, 134 patients (mean age = 40.4 years, 80.7% female) underwent open Roux-en-Y gastric bypass (44% mesh, 56% nonmesh). Twenty-eight patients were excluded from the analysis secondary to a short follow-up period (mesh = 13, nonmesh = 11) and/or reoperative surgery unrelated to the development of an incisional hernia (mesh = 2, nonmesh = 2). The mean follow-up period was 17.3 ± 8.5 months (mesh, 16.6 ± 7.1; nonmesh, 17.7 ± 9.4, $P = 0.50$). No significant difference was noted between the mesh and nonmesh groups with regard to age ($P = 0.06$), gender ($P = 0.10$), preoperative body mass index (BMI) ($P = 0.26$), total weight loss ($P = 0.53$), diabetes ($P = 0.89$), sleep apnea ($P = 0.22$), asthma ($P = 0.06$), exertional dyspnea ($P = 0.12$), depression ($P = 0.65$), hypertension ($P = 0.36$), degenerative joint disease ($P = 0.94$), smoking ($P = 0.31$), and wound infection ($P = 0.07$) (Table 1). Patients in the nonmesh group were more likely to have undergone prior abdominal surgery ($P = 0.001$), while those in the mesh group had an overall lower postoperative BMI ($P = 0.05$) at the time of last follow-up. The overall incidence of incisional hernia was 11.3% (95% CI: 5.19–17.45). The incidence of incisional hernia was significantly lower in the mesh group (mesh: 2.3%, 95% CI: −2.31-6.86; nonmesh: 17.7%, 95% CI: 7.96–27.52, $P = 0.01$), while the incidence of seroma was lower in the nonmesh group (mesh, 13.64%; nonmesh, 1.64%, $P = 0.01$) (Table 1). In a multivariate logistic regression model that adjusted for age, sex, BMI, albumin, smoking, diabetes, prior surgery, seroma formation, weight loss, and mesh placement, hernia was found to be associated with smoking (adjusted odds ratio [OR] 8.46, 95% CI: 1.79–40.00, $P = 0.008$) while prophylactic mesh was noted to be protective against incisional hernia development (adjusted OR: 0.06, 95% CI: 0.006–0.69, $P = 0.02$) (Table 2).

Discussion

Since its first description in 1975 by Dr. Rene Stoppa, an abundance of data has emerged supporting the superiority

Table 1 Patient demographics and characteristics

Variable	Nonmesh [62 (58.5%)] *n* (%)	Mesh [44 (41.5%)] *n* (%)	*P* value[a]
Age (mean ± SD)	39.39 ± 11.08	43.73 ± 11.81	0.06
Gender			0.10
Male	10 (16.13%)	13 (29.55%)	
Female	52 (83.87%)	31 (70.45%)	
Preoperative BMI (mean ± SD)	50.38 ± 9.31	52.58 ± 10.59	0.26
Postoperative BMI (mean ± SD)	33.48 ± 8.56	36.75 ± 7.73	0.05
Weight loss (mean ± SD)	103.25 ± 63.74	96.18 ± 46.16	0.53
Preoperative albumin (mean ± SD)	4.04 ± 0.32	3.92 ± 0.26	0.14
Diabetes	21 (33.87%)	14 (32.56%)	0.89
Sleep apnea	12 (19.35%)	13 (29.55%)	0.22
Asthma	18 (29.03%)	6 (13.64%)	0.06
Hypothyroidism	4 (6.75%)	5 (11.36%)	0.37
Exertional dyspnea	23 (37.10%)	10 (22.73%)	0.12
Prior abdominal surgery	33 (54.10%)	10 (22.73%)	0.001
Depression	15 (24.19%)	9 (20.45%)	0.65
Hypertension	31 (50.00%)	18 (40.91%)	0.36
Degenerative joint disease	58 (93.55%)	41 (93.18%)	0.94
Smoking			0.31
No	49 (79.03%)	31 (70.45%)	
Yes	13 (20.97%)	13 (29.55%)	
Incisional hernia	11 (17.74%)	1 (2.27%)	0.01
Wound infection	1 (1.61%)	4 (9.09%)	0.07
Seroma	1 (1.61%)	6 (13.64%)	0.01
Follow-up period (mean ± SD)	17.72 ± 9.39	16.59 ± 7.05	0.50

[a] Fisher's exact test

of tension-free mesh repair over primary suture repair in the management of incisional hernias [5–11]. At present, tension-free mesh repair is standard in the operative management of incisional hernias, having proven to be efficacious even in the face of multiple non-modifiable patient-related risk factors, decreasing the incidence of recurrence by as much as 50% in some series [10]. From this success and fostered by an era of newer biologic mesh that can safely be used in spite of intra-abdominal contamination, the question arises: Can abdominal wall closure with permanent mesh be similarly used to prevent, rather than repair, incisional hernias? Some of the data are promising.

Strzelczyk et al. [13], in a nonrandomized prospective study of patients who underwent open Roux-en-Y gastric bypass, found no hernias in the prophylactic mesh group ($n = 12$) and nine in the standard closure group ($n = 48$). A follow-up randomized controlled study by Strzelczyk et al. [14] again found that none of the patients assigned to the prophylactic polypropylene mesh group ($n = 36$) developed incisional hernias while one-fifth of those in the primary closure group ($n = 38$) did. Similarly, Gutiérrez de la Peña et al. [15] found prophylactic polypropylene mesh placement to be protective against incisional hernia development when they randomized a 100 patients to either primary abdominal wall closure or supra-aponeurotic polypropylene mesh placement. At 3-year follow-up, five patients in the nonmesh group had developed incisional hernias while all in the mesh group were without hernia ($P = 0.02$) [15]. In contrast to these positive findings, Pan et al. [19] were unable to show any reduction in incisional hernia development with the prophylactic use of a polyglactin mesh. Their study, however, differs dramatically from the other cited studies in that an absorbable mesh was used, placed intraperitoneally without fixation, and the overlying fascia was approximated with interrupted absorbable suture [19].

The incisional hernia rate following nonmesh closure in our series was 17.7%, a rate similar to that reported in the literature [1–3, 20]. Patients who received prophylactic mesh placement, however, experienced a significantly lower incisional hernia rate (2.3%), with the only added morbidity being increased seroma formation (mesh, 13.6%; nonmesh, 1.6%, $P = 0.01$). However, seroma formation following hernia repair with mesh is a common occurrence, with some laparoscopic series reporting a 35% incidence discovered clinically, and a 100% found on subsequent ultrasonic evaluation [21]. These findings have led many to consider it an expected mesh-related reaction rather than a

Table 2 Comparison of the hernia and nonhernia groups

Variable	Hernia group [12 (11.3%)] *n* (%)	Nonhernia group [94 (88.7%)] *n* (%)	*P* value[a]
Biologic mesh use	1 (8.33%)	43 (45.74%)	0.01
Follow-up period (mean ± SD)	18.01 ± 9.51	17.16 ± 8.03	0.47
Age (mean ± SD)	39.75 ± 12.75	41.37 ± 11.47	0.64
Gender			0.46
Male	1 (8.33%)	22 (23.40%)	
Female	11 (91.67%)	72 (76.60%)	
Preoperative BMI (mean ± SD)	53.36 ± 7.54	51.03 ± 10.13	0.44
Postoperative BMI (mean ± SD)	33.13 ± 7.29	35.06 ± 8.49	0.45
Weight loss (mean ± SD)	125.75 ± 38.73	97.07 ± 58.24	0.10
Preoperative albumin (mean ± SD)	3.87 ± 0.31	4.01 ± 0.30	0.13
Diabetes	6 (50.00%)	29 (31.18%)	0.21
Sleep apnea	1 (8.33%)	24 (25.53%)	0.29
Asthma	2 (16.67%)	22 (23.40%)	0.73
Prior abdominal surgery	6 (50.00%)	37 (39.78%)	0.54
Smoking			0.008
No	5 (41.67%)	75 (79.79%)	
Yes	7 (58.33%)	19 (20.21%)	
Wound infection	0 (0.00%)	5 (5.32%)	1.00
Seroma	1 (8.33%)	6 (6.38%)	0.58

BMI Body mass index

[a] Fisher's exact test

complication, a small price to pay for a sturdier repair or in our case a diminutive incisional hernia rate.

Given the current emphasis on health-care cost containment, novel interventions need not only be safe and efficacious but also financially responsible prior to their adoption. Simply stated, is a potential improvement in incisional hernia rate worth the additional expense associated with routine biologic mesh placement? Although a formal cost analysis was not conducted, routine use of a biologic mesh in high-risk patients may be a financially desirable proposition. Of the 12 incisional hernias identified, 9 were symptomatic requiring repair. Taking into account the cost of biologic mesh (44 patients × $1,700 = $77,000) and the average cost of an incisional hernia repair ($16,947) [22], in our cohort a 15.4% reduction in incisional hernia rate (6.7 hernia repairs avoided = $113,544 savings) came with an additional $36,544 in savings. This estimate is conservative seeing that it fails to take into account wages lost by patients, costs associated with failed hernia repairs, and more importantly the emotional and physical duress of patients who undergo a second operation.

This is the first study to demonstrate the benefit obtained from prophylactic biologic mesh placement at the time of midline laparotomy in patients at high risk for the development of incisional hernia. Although the study was limited to patients undergoing open Roux-en-Y gastric bypass, we believe these results apply to patients with recognized risk factors for incisional hernia development such as diabetes, morbid obesity, and a history of smoking. Furthermore, as the price of biologic mesh declines, the observed improvement in incisional hernia rate may not only translate to better patient care, but also into overall cost containment. The conclusions from this study will be more compelling in the future with a larger sample size, prospective randomization, and thorough cost analysis.

References

1. Mudge M, Hughes LE (1985) Incisional hernia: a ten year prospective study of incidence and attitudes. Br J Surg 72:70–71
2. Bucknall TE, Cox PJ, Ellis H (1982) Burst abdomen and incisional hernia: a prospective study of 1129 major laparotomies. Br Med J (Clin Res Ed) 284(6364):519–520
3. Livingston EH (2005) Complications of bariatric surgery. Surg Clin North Am 85:853–868
4. Shell DH, de la Torre J, Andrades P, Vasconez LO (2008) Open repair of ventral incisional hernias. Surg Clin North Am 88(1): 61–83
5. George CD, Ellis H (1986) The results of incisional hernia repair: a twelve year review. Ann R Coll Surg Engl 68:185–187
6. Stoppa RE (1989) The treatment of complicated groin and incisional hernias. World J Surg 13:545–554. doi:10.1007/BF01658869
7. Leber GE, Garb JL, Alexander AI, Reed WP (1998) Long-term complications associated with prosthetic repair of incisional hernias. Arch Surg 133:378–382

8. Morris-Stiff GJ, Hughes LE (1998) The outcomes of nonabsorbable mesh placed within the abdominal cavity: literature review and clinical experience. J Am Coll Surg 186:352–367
9. Luijendijk RW, Hop WC, van den Tol MP, de Lange DC, Braaksma MM, IJzermans JN, Boelhouwer RU, de Vries BC, Salu MK, Wereldsma JC, Bruijninckx CM, Jeekel JJ (2000) A comparison of suture repair with mesh repair for incisional hernia. N Engl J Med 343(6):392–398
10. Korenkov M, Sauerland S, Arndt M, Bograd L, Neugebauer EAM, Troidl H (2002) Randomized clinical trial of suture repair, polypropylene mesh or autodermal hernioplasty for incisional hernia. Br J Surg 89:50–56
11. Burger JW, Luijendijk RW, Hop WC, Halm JA, Verdaasdonk EG, Jeekel J (2004) Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg 240:578–585
12. Bellón JM, López-Hervás P, Rodríguez M, García-Honduvilla N, Pascual G, Buján J (2006) Midline abdominal wall closure: a new prophylactic mesh concept. J Am Coll Surg 203(4):490–497
13. Strzelczyk J, Czupryniak L, Loba J, Wasiak J (2002) The use of polypropylene mesh in midline incision closure following gastric by-pass surgery reduces the risk of postoperative hernia. Langenbecks Arch Surg 387(7–8):294–297
14. Strzelczyk JM, Szymański D, Nowicki ME, Wilczyński W, Gaszynski T, Czupryniak L (2006) Randomized clinical trial of postoperative hernia prophylaxis in open bariatric surgery. Br J Surg 93(11):1347–1350
15. Gutiérrez de la Peña C, Medina C, Dominguez E, Medina J (2003) Primary closure of laparotomies with high risk of incisional hernia using prosthetic material: analysis of usefulness. Hernia 7:134–136
16. O'Hare JL, Ward J, Earnshaw JJ (2007) Late results of mesh wound closure after elective open aortic aneurysm repair. Eur J Vasc Endovasc Surg 33(4):412–413
17. Kim H, Bruen K, Vargo D (2006) Acellular dermal matrix in the management of high-risk abdominal wall defects. Am J Surg 192(6):705–709
18. Patton JH Jr, Berry S, Kralovich KA (2007) Use of human acellular dermal matrix in complex and contaminated abdominal wall reconstructions. Am J Surg 193(3):360–363
19. Pans A, Elen P, Dewé W, Desaive C (1998) Long-term results of poly-glactin mesh for the prevention of incisional hernias in obese patients. World J Surg 22:479–483. doi:10.1007/s002689900420
20. Horowitz MI, Leitman IM (2008) Risk factors for the development of incisional hernia following Roux-en-Y gastric bypass surgery. Open Surg J 2:15–17
21. Susmallian S, Gewurtz G, Ezri T, Charuzi I (2001) Seroma after laparoscopic repair of hernia with PTFE patch: is it really a complication? Hernia 5(3):139–141
22. Finn KR, Kilgore ML, Hawn MT (2009) Open suture versus mesh repair of primary incisional hernias: a cost-utility analysis. Hernia 13(2):173–182